JUN 19 2013

MERIT MEDICAL SYSTEMS, INC
1600 WEST MERIT PARKWAY
SOUTH JORDAN, UTAH 84095
PHONE 801-253-1600
FAX 801-253-1688
www.merit.com

1 510(k) Summary

General Provisions	Correspondent Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 801-208-4408 801-253-6945 Dan W. Lindsay March 1, 2013 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	basixTOUCH™ Inflation Syringe MAV Balloon Inflation Syringe
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Merit basixCOMPAK™ Inflation Syringe MAV Balloon Inflation Syringe K122321 Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 870.1650, MAV Division of Cardiovascular Devices	
Intended Use	The basixTOUCH Inflation Syringe is used to inflate and deflate an angioplasty balloon or other interventional device, and to measure the pressure within the balloon	
Device Description	The basixTOUCH Inflation Syringe is a single use disposable device capable of generating and monitoring pressure in angioplasty or other similar interventional devices. It is fitted with a threaded plunger assembly with lock/release bar, flexible high pressure extension tube.	

Comparison to Predicate	The Technological characteristics of the subject basixTOUCH inflation syringe are substantially equivalent to those of the predicate, the Merit basixCOMPAK Inflation Syringe. The basixTOUCH generates higher pressure and is a larger volume syringe than the Predicate.
Safety & Performance Tests	No applicable mandatory performance standards or special controls have been established under Section 514 of the Food, Drug and Cosmetic Act for this device. However, a battery of tests was performed according to protocols based on the requirements of industry standards and guidance and the device met the acceptance criteria necessary to demonstrate the safety and efficacy of the device. Where appropriate, the tests were based on the requirements of the following documents: • ISO 11135-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices. • ISO 10993-7:2008 - Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals • ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. • ASTM D4169 - 09 Standard Practice for Performance Testing of Shipping Containers and Systems • ISO 10993-1: 2009 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process, and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1.

Safety & Performance Tests	The following is a list of all significant performance testing that has been successfully completed for this device: Device Testing • Fluid Functional Use • Gauge Accuracy • Gauge Tensile • Retainer Cap Bond Torque • Tip Adapter Securement • Tip Securement • Vacuum Capability Packaging Testing • Visual Inspection • Dye Penetration • Underwater Leak Test • Burst Strength Test
Summary of Substantial Equivalence	Based on the indications for use, design, safety, and performance testing, the subject basixTOUCH Inflation Device meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Merit basixCompak Analog Inflation Syringe (K122321) manufactured by Merit Medical Systems, Inc. Differences between the devices do not raise any different questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 19, 2013

Merit Medical Systems
Dan Lindsay, RAC
Regulatory Affairs Specialist III
2306 Sunnyside Avenue
Salt Lake City, UT 84108

Re: K130566
Trade/Device Name: BasixTOUCH
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: MAV
Dated: May 23, 2013
Received: May 24, 2013

Dear Mr. Lindsay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known): K130566

Device Name: basixTOUCH™

Indications for Use:

The basixTOUCH inflation syringe is used to inflate and deflate an angioplasty balloon or other interventional device, and to measure the pressure within the balloon.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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